DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

URGENT DEVICE RECALL

APR 16 2002

Dear Customer:

In accordance with section 518(e)(2) of the Federal Food, Drug, and Cosmetic Act (the Act), the Food and Drug Administration (FDA) has ordered A & A Medical, Inc., doing business as LifeQuest Medical, Inc., and Rocket USA (A & A), to conduct a recall of all lots of medical devices labeled as "Sterile" or "Ethylene Oxide Processed", manufactured and distributed during the last three (3) years by the firm. The firm is located in Alpharetta, Georgia.

FDA has determined that there is a reasonable probability that use of these devices would cause serious, adverse health consequences or death because, contrary to their labeling, they may **not** have been subjected to a sterilization process. Please check your inventory, and stop using and distributing these devices. *We encourage voluntary destruction of all recalled devices.* We are requesting that you complete the enclosed Self-Certification Form that includes information on the status of your firm and sub-distributors and information on all devices to be destroyed. The Self-Certification Form should be sent by facsimile to FDA's Atlanta District Office (ATL-DO) Recall Coordinator, Sheryl Cruse at (404) 253-1201. Ms. Cruse should also be notified of the place, date, and time when the devices will be destroyed, in the event FDA chooses to witness the destruction. Please fax a copy of the completed form to A & A's legal representative, Mr. Orrin Walker at (770)-432-3029.

If you have distributed any of these devices, as labeled above or under your own label or any other label, we request that you sub-recall by immediately contacting your accounts. Provide them with a copy of this notification. Request that they cease use and distribution, and have them promptly return the recalled devices to you. Alternatively, they may destroy the products themselves if you account for the devices by using a copy of the enclosed Self-Certification Form. Follow the same procedure as described above. Notify Sheryl Cruse, ATL-DO, immediately if any user or distributor refuses to comply with this notification at (404) 253-1278.

Please be advised that A & A may no longer be in operation and has not provided a responsible party to receive and store recalled devices. FDA has had a number of inquiries about re-sterilization of these devices. It cannot be determined which of these devices have already been sterilized. FDA is not aware of any data that would establish conditions for the safe and effective cleaning and subsequent re-sterilization of these disposable medical devices. Therefore, FDA does not recommend sterilization/re-sterilization.

FDA has prepared a "Q & A" (on reverse side) that may help answer questions. Written correspondence and inquiries should be addressed to the ATL-DO at 60 Eighth Street NE, Atlanta, GA 30309, ATTN: Sheryl Cruse. Telephone inquiries may be directed to FDA's Center for Devices and Radiological Health (CDRH), Division of Small Manufacturers and International Consumer Assistance (DSMICA) at (800) 638-2041. Inquiries may also be made to Mr. Orrin Walker, the firm's legal representative, 2291 Austell Road, Suite 107, Marietta, Georgia 30008, (770)-801-8600.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices
and Radiological Health

Enclosures